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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,429	09/26/2003	Robert O. Dempcy	17682A-003650US	1810
20350 7590 11/28/2007 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER BRUSCA, JOHN S	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 11/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/672,429	Applicant(s) DEMPCY ET AL.	
	Examiner John S. Brusca	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 110-127 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 110-127 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This application has been transferred to a new examiner.

Priority

2. The applicants filed an amendment to the priority claim in the first sentence of the specification on 26 September 2003, and an Application Data Sheet on the same day, 26 September 2003. While the amendment to the specification details priority to seven applications, the application data sheet only lists one application. Rule 37 CFR 1.76(d)(2) states that “ The information in the application data sheet will govern when the inconsistent information is supplied at the same time by an amendment to the specification.” However the application whose priority is claimed in the application data sheet (Application No. 09/796,988) claims priority to many of the applications listed in the amendment to the specification. In addition it is apparent from the application file that the applications listed in the preliminary amendment, as well as an application listed on the transmittal sheet filed 26 September 2003 (Application No. 10/032,307) were recognized by the Office as claimed under 35 U.S.C. 120 for domestic priority. According to the MPEP 201.11 III D, if the Office recognizes a claim for priority, the applicants may perfect any deficiencies in their statement of priority without the necessity of filing a petition under 37 CFR 1.78. Therefore, to perfect the claim for priority the applicants must amend the specification or file a supplemental application data sheet to include all intended applications claimed under 35 U.S.C. 120. **Without such an amendment or filing of a supplemental application data sheet the priority claim will remain that claimed in the application data sheet filed 26 September 2003.**

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It is further noted that the amendment to the specification filed 26 September 2003 contains claims to applications whose stated relationship is improper because of a lack of copendency. The instant Application No. 10/672,429 cannot be a CIP of Application Nos. 09/640,953 or 09/431,385 because the two applications do not have copendency with the instant application.

In an amendment to the priority claim, the applicants may wish to:

- a) claim the instant application as a CON of Application No. 10/032,307
- b) claiming Application No. 09/724,959 as a CIP of Application No. 09/640,953
- c) claiming Application No. 09/724,959 as a CIP of Application No. 09/431,385.

3. It is brought to the applicant's attention that, for the purpose of examination, **benefit** of the claimed priority has not been granted to the claimed prior Application Nos. (as recognized by the Office in the filing receipt) 60/186,046, 09/640,953, 09/054,832, 09/431,385, and 09/054,830 because the applications do not disclose nearest-neighbor methods for the calculation of melting temperatures or duplex stability as recited in the instant claimed subject matter.

Drawings

4. The drawings were received on 14 March 2007. These drawings are accepted.

Specification

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5. The objection to the abstract in the Office action mailed 14 September 2006 is withdrawn in view of the amended abstract filed 20 September 2007.

6. The objection to the specification in the Office action mailed 14 September 2006 is withdrawn in view of the amendment filed 14 March 2007.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 110-127 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 110-127 are drawn to a process. A statutory process must include a step of a physical transformation, or produce a useful, concrete, and tangible result (*State Street Bank & Trust Co. v. Signature Financial Group Inc.* CAFC 47 USPQ2d 1596 (1998), *AT&T Corp. v. Excel Communications Inc.* (CAFC 50 USPQ2d 1447 (1999))). The instant claims do not result in a physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be “useful,” the claim must produce a result that is specific, and substantial. For a claim to be “concrete,” the

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process must have a result that is reproducible. For a claim to be “tangible,” the process must produce a real world result . Furthermore, the claim must be limited only to statutory embodiments.

Claims 110-127 do not require production of a tangible result in a form that is useful to the user of the process or apparatus. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the process is outputted to a display, or to a user, or in a graphical format, or in a user readable format, or by including a result that is a physical transformation. The applicants are cautioned against introduction of new matter in an amendment.

Claim Rejections - 35 USC § 112

9. The rejection of claims 110-127 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention in the Office action mailed 14 September 2006 is withdrawn in view of the amendment filed 14 March 2007.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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11. Claim 124 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 124 depends from claims 110 or 111. The independent claims do not recite a tangible result as noted above because there is no explicit result outputted to a user or the claimed method does not result in an explicit physical transformation. Prior to the amendment filed 14 March 2007 claim 124 was not rejected for nonstatutory subject matter because the claim recited the phrase “wherein said method is applied **in establishing** appropriate conditions for hybridization, renaturation, mapping variations of base compositions of sequences or determination of sequence complexity and divergence” (emphasis added) which was interpreted as requiring that the recited physical steps were performed. In the amendment filed 14 March 2007, claim 124 was amended to recite “wherein said method is applied **to establish** appropriate conditions for hybridization, renaturation, mapping variations of base compositions of sequences or determination of sequence complexity and divergence” (emphasis added). The amendment to claim 124 was not apparently in response to any rejection or objection of record and the applicants did not comment on the reasons for the amendment in their arguments filed concurrently with the amendment. It is not clear if a result that is a physical transformation is still required in the method of claim 124, or if the wherein clause is merely an intended use that is not an actual claimed step of the method of claim 124. New grounds of rejection for claim 124 have been applied under 35 U.S.C. 101 for nonstatutory subject matter as noted above. Appropriate amendment of the independent claims 110 and 111 to explicitly require a tangible result or a

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result that is a physical transformation would overcome this rejection of claim 124 for indefiniteness.

Claims 110-117 and 119-127 are indefinite because the claims are drawn to methods that use oligonucleotides that comprise modified bases that can be unsubstituted pyrimidines because unsubstituted pyrimidines are naturally occurring bases that are not modified.

Claims 116 and 127 are indefinite because the claims are drawn to methods that use oligonucleotides that comprise bases that are locked nucleic acid sugars, while it is conventional in the art to consider a nucleotide to comprise two portions, a base and a sugar, which are mutually exclusive portions of the nucleotide.

Claim Objections

12. The objection to claim 116 in the Office action mailed 14 September 2006 is withdrawn in view of the amendment filed 14 March 2007.

Claim Rejections - 35 USC § 102

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13. The rejection of claims 110-113 and 118-122 under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter in the Office action mailed 14 September 2006 is withdrawn in view of the declaration under 37 CFR 1.132 filed 14 March 2007 stating that the commonly claimed subject matter is not by a different entity then Lokhov et al., and further because the Office did not provide evidence of derivation of the claimed subject matter by the applicants from another.

14. The rejection of claims 110-113 and 118-122 under 35 U.S.C. 102(e) as being anticipated by Lokhov et al. (US Publication #20030235822, December 25th, 2003) with a priority date of 11/28/00 in the Office action mailed 14 September 2006 is withdrawn in view of the declaration under 37 CFR 1.132 establishing that the instant claimed subject matter described in Lokhov et al. is not by a different entity, and the common effective filing date of the instant application and Lokhov et al.

15. The rejection of claims 110-113 and 118-122 under 35 U.S.C. 102(e) as being anticipated by Lizardi et al. (U.S. Patent No. 6,403,319) in the Office action mailed 14 September 2006 is withdrawn in view of the amendment filed 14 March 2007 and the lack of explicit showing of nearest neighbor analysis related to oligonucleotide duplex stability.

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 110, 114, 115, and 123 are rejected under 35 U.S.C. 102(b) as being anticipated by Griffin et al. (Analytical Biochemistry, Vol. 260, pages 56-63, 1998).

Claim 110 is drawn to a method of calculating the duplex stability of an oligonucleotide comprising unsubstituted pyrimidines using a nearest-neighbor model. Claims 114 and 115 further limit the method of claim 110 to use of peptide nucleic acids. Claim 123 further limits the method of claim 110 to an accuracy of prediction of a melting temperature within 2 degrees Celsius.

Griffin et al. disclose a method for calculating the duplex stability and melting temperature of nucleic acids modified with PNA using nearest neighbor models (see abstract, lines 1-6 and 17-18).

Regarding claims 114 and 115, Griffin et al. disclose the use of PNA as the base modification in the abstract and throughout.

Regarding claim 123, Griffin et al. disclose that their average difference between calculated and measured duplexes was 2.2 degrees, reasonably about 2 degrees (page 59, 1st column, paragraph 5, lines 4-6).

18. Applicant's arguments filed 14 March 2007 have been fully considered but they are not persuasive.

The applicants state that Griffin et al. does not show analysis of modified bases, however the rejected claims read on analysis of unmodified bases because the claimed subject matter includes analysis of nucleic acids that comprise unsubstituted pyrimidines.

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Claim Rejections - 35 USC § 103

18. The rejection of claims 110-114, 117-124 under 35 U.S.C. 103(a) as being unpatentable over Schutz et al. in view of Kutuyavin et al. in the Office action mailed 14 September 2006 is withdrawn in view of the arguments filed 14 March 2007.

19. The rejection of claims 110-114, 116-117, 123-124, and 127 under 35 U.S.C. 103(a) as being unpatentable over Schutz et al. in view of Singh et al. in the Office action mailed 14 September 2006 is withdrawn in view of the arguments filed 14 March 2007.

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 110-116 and 118-121 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 6-9 of copending Application No. 10/176,972. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to design the oligonucleotide sequence predicted by the method of Application No. 10/176,972, and because the melting temperature determination of the method of Application No. 10/176,972 is a species of the duplex stability measurement of instant claim 110.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John S. Brusca/

Primary Examiner

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jsb